

CLAIMS

1. A biosensor for quantifying a substrate included in a sample liquid comprising:

a first insulating support and a second insulating support;

an electrode part comprising at least a working electrode and a counter electrode;

a specimen supply path for introducing the sample liquid to the electrode part; and

a reagent layer employed for quantifying the substrate included in the sample liquid,

the electrode part, the specimen supply path, and the reagent layer existing between the first insulating support and the second insulating support,

the specimen supply path being provided on the electrode part, and the reagent layer being provided on the electrode part in the specimen supply path, respectively, and

the electrode part being dividedly formed by first slits provided on an electrical conductive layer which is formed on the whole or part of an internal surface of one or both of the first insulating support and the second insulating support.

2. The biosensor as defined in Claim 1, wherein

the electrode part further comprises a detecting electrode.

3. The biosensor as defined in Claim 2, wherein the counter electrode is provided on the whole or part of the internal surface of the second insulating support, the working electrode and the detecting electrode are provided on the whole or part of the internal surface of the first insulating support, and the working electrode and the detecting electrode which are provided on the internal surface of the first insulating support are dividedly formed by the first slits provided on the electrical conductive layer.

40 The biosensor as defined in Claim 1 or 2, wherein
 50 the electrode part is provided on the whole or part of
 60 the internal surface of only the first insulating support, and
 70 the electrode part provided on the internal surface of
 80 the first insulating support is dividedly formed by the first
 90 slits provided on the electrical conductive layer.

5. The biosensor as defined in any of Claims 1 to 4, wherein an area of the counter electrode is equal to or larger than that of the working electrode.
6. The biosensor as defined in any of Claims 1 to 4, wherein a total of an area of the counter electrode and an area of the detecting electrode is equal to or larger than that of the working electrode.
7. The biosensor as defined in Claim 6, wherein the area of the detecting electrode in the specimen

supply path of the biosensor is equal to the area of the counter electrode.

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The biosensor as defined in any of Claims 1 to 7, wherein a spacer is provided which has a cutout part for forming the specimen supply path and is placed on the electrode part, and

the second insulating support is placed on the spacer.

9. The biosensor as defined in Claim 8, wherein

the spacer and the second insulating support is integral.

10. The biosensor as defined in any of Claims 1 to 9, wherein an air hole leading to the specimen supply path is formed.

11. The biosensor as defined in any of Claims 1 to 10, wherein the reagent layer is formed by dripping a reagent, and second slits are provided around a position where the reagent is dripped.

12. The biosensor as defined in Claim 11, wherein

the second slits are arc shaped.

13. The biosensor as defined in any of Claims 1 to 12, wherein third slits are provided for dividing the electrical conductive layer to define an area of the electrode part.

14. The biosensor as define in Claim 13, wherein

shapes of the first insulating support and the second insulating support are approximately rectangular, and

one third slit or two or more third slits are provided in parallel with one side of the approximate rectangle shape.

~~415~~ The biosensor as defined in any of Claims 1 to 14 having information of correction data generated for each production lot of the biosensor, which correspond to characteristics concerning output of an electrical change resulting from a reaction between the sample liquid and the reagent layer and can be discriminated by a measuring device employing the biosensor.

16. The biosensor as defined in Claim 15, wherein one or plural fourth slits dividing the electrode part are provided, and the measuring device can discriminate the information of the correction data according to positions of the fourth slits.

~~415~~ The biosensor as defined in any of Claims 1 to 16, wherein at least one or all of the first slits, the second slits, the third slits, and the fourth slits are formed by processing the electrical conductive layer by a laser.

18. The biosensor as defined in Claim 17, wherein a slit width of respective one of the first slits, the second slits, the third slits, and the fourth slits is 0.005 mm to 0.3 mm.

~~Sub 19. Art~~ The biosensor as defined in Claims 17 and 18, wherein a slit depth of respective one of the first slits, the second slits, the third slits, and the fourth slits is equal to or larger than the thickness of the electrical conductive layer.

20. The biosensor as defined in any of Claims 1 to 19,
wherein

the reagent layer includes an enzyme.

21. The biosensor as defined in any of Claims 1 to 19,
wherein

the reagent layer includes an electron transfer agent.

22. The biosensor as defined in any of Claims 1 to 19,
wherein

the reagent layer includes a hydrophilic polymer.

23. The biosensor as defined in any of Claims 1 to 22,
wherein

the insulating support is made of a resin material.

24. A thin film electrode forming method for forming a thin
film electrode on a surface of an insulating support including:
a roughened surface forming step of roughening the surface
of the insulating support by colliding an excited gas against
the surface of the insulating support in a vacuum atmosphere;
and

an electrical conductive layer forming step of forming the
electrical conductive layer as a thin film electrode which is
composed of a conductive substance on the roughened surface of
the insulating support.

25. The thin film electrode forming method as defined in
Claim 24, wherein

the roughened surface forming step comprises:

a support placing step of placing the insulating support in a vacuum chamber;

an evacuation step of evacuating the vacuum chamber;

a gas filling step of filling up the vacuum chamber with a gas; and

a colliding step of exciting the gas to be ionized and colliding the same against the insulating support.

26. The thin film electrode forming method as defined in Claim 25, wherein

a degree of the vacuum in the evacuation step is within a range of 1×10^{-1} to 3×10^{-3} pascals.

27. The thin film electrode forming method as defined in Claim 26, wherein

the gas is an inert gas.

28. The thin film electrode forming method as defined in Claim 27, wherein

the inert gas is either a rare gas of argon, neon, helium, krypton, and xenon, or nitrogen.

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48 29. The thin film electrode forming method as defined in any of Claims 24 to 28, wherein

the electrical conductive layer forming step comprises:

a second support placing step of placing an insulating support having an already roughened surface, which has been subjected to the roughened surface forming step, in a second vacuum chamber;

a second evacuation step of evacuating the second vacuum chamber;

a second gas filling step of filling up the second vacuum chamber with a second gas; and

a step of exciting the second gas to be ionized and colliding the same against a conductive substance to beat out atoms of the conductive substances, to form a film on the insulating support having the already roughened surface.

30. The thin film electrode forming method as defined in any of Claims 24 to 28, wherein

the electrical conductive layer forming step comprises:

a second support placing step of placing an insulating support having an already roughened surface, which has been subjected to the roughened surface forming step, in a second vacuum chamber;

a second evacuation step of evacuating the second vacuum chamber; and

a step of heating and evaporating a conductive substance to deposit steams as a film on the insulating support having the already roughened surface.

31. The thin film electrode forming method as defined in Claim 29 or 30, wherein

a degree of the vacuum in the second evacuation step is within a range of 1×10^{-1} to 3×10^{-3} pascals.

32. The thin film electrode forming method as defined in any

of claims 29 to 31, wherein

the second gas is an inert gas.

33. The thin film electrode forming method as defined in claim 32, wherein

the inert gas is either a rare gas of argon, neon, helium, krypton and xenon, or nitrogen.

34. The thin film electrode forming method as defined in any of claims 29 to 31, wherein

the vacuum chamber and the second vacuum chamber is the same chamber.

35. The thin film electrode forming method as defined in any of claims 29 to 34, wherein

the conductive substance is a noble metal or carbon.

36. The thin film electrode forming method as defined in any of claims 24 to 35, wherein

a thickness of a formed thin film electrode is within a range of 3 nm to 100 nm.

37. The biosensor as defined in any of claims 1 to 23, wherein

the electrical conductive layer is formed by

the thin film electrode forming method as defined in any of claims 24 to 36.

38. A quantification method for quantifying, by employing the biosensor as defined in any of claims 1 to 23 and 37, a substrate included in a sample liquid supplied to the biosensor

comprising:

a first application step of applying a voltage between the detecting electrode and the counter electrode or the working electrode;

a sample liquid supplying step of supplying the sample liquid to the reagent layer;

a first change detecting step of detecting an electrical change occurring between the detecting electrode and the counter electrode or the working electrode by the supply of the sample liquid to the reagent layer;

a second application step of applying a voltage between the working electrode and the counter electrode as well as the detecting electrode after the electrical change is detected in the first change step; and

a current measuring step of measuring a current generated between the working electrode and the counter electrode as well as the detecting electrode, to which the voltage is applied in the second application step.

39. A quantification method for quantifying, by employing the biosensor as defined in any of claims 1 to 23 and 37, a substrate included in a sample liquid supplied to the biosensor comprising:

a third application step of applying a voltage between the detecting electrode and the counter electrode or the working electrode as well as between the working electrode and the

counter electrode;

a sample liquid supplying step of supplying the sample liquid to the reagent layer;

a first change detecting step of detecting an electrical change occurring between the detecting electrode and the counter electrode or the working electrode by the supply of the sample liquid to the reagent layer;

a second change detecting step of detecting an electrical change occurring between the working electrode and the counter electrode by the supply of the sample liquid to the reagent layer;

179 a second application step of applying a voltage between the working electrode and the counter electrode as well as the detecting electrode after the electrical changes are detected in the first change detecting step and the second change detecting step; and

a current measuring step of measuring a current generated between the working electrode and the counter electrode as well as the detecting electrode, to which the voltage is applied in the second application step.

40. The quantification method as defined in Claim 38 or 39, wherein

the second change detecting step is followed by

a no-change informing step of informing a user that no change occurs when it is detected that no electrical change

occurs between the detecting electrode and the counter electrode or the working electrode for a prescribed period of time.

41. A quantification apparatus, to which the biosensor as defined in any of Claims 1 to 23 and 37 is detachably connected and which quantifies a substrate included in a sample liquid supplied to the biosensor comprising:

1719 a first current/voltage conversion circuit for converting a current from the working electrode included in the biosensor into a voltage;

a first A/D conversion circuit for digitally converting the voltage from the current/voltage conversion circuit;

a first switch provided between the counter electrode included in the biosensor and the ground; and

a control part for controlling the first A/D conversion circuit and the first switch,

the control part

applying a voltage between the detecting electrode and the working electrode in a state where the first switch is insulated from the counter electrode,

detecting an electrical change between the detecting electrode and the working electrode occurring by the sample liquid which is supplied to the reagent layer on the specimen supply path,

thereafter applying a voltage between the working

electrode and the counter electrode as well as the detecting electrode in a state where the first switch is connected to the counter electrode, and

measuring a current generated by applying the voltage.

42. A quantification apparatus, to which the biosensor as defined in any of Claims 1 to 23 and 37 is detachably connected and which quantifies a substrate included in a sample liquid supplied to the biosensor comprising:

a first current/voltage conversion circuit for converting a current from the working electrode included in the biosensor into a voltage;

a second current/voltage conversion circuit for converting a current from the detecting electrode included in the biosensor into a voltage;

a first A/D conversion circuit for digitally converting the voltage from the first current/voltage conversion circuit;

a second A/D conversion circuit for digitally converting the voltage from the second current/voltage conversion circuit;

a first selector switch for switching the connection of the detecting electrode of the biosensor to the first current/voltage conversion circuit or the ground; and

a control part for controlling the first A/D conversion circuit, the second A/D conversion circuit, and the first selector switch,

the control part

applying a voltage between the detecting electrode and the counter electrode as well as between the working electrode and the counter electrode in a state where the first selector switch is connected to the first current/voltage conversion circuit,

detecting an electrical change between the detecting electrode and the working electrode as well as an electrical change between the working electrode and the counter electrode, respectively, occurring by the sample liquid which is supplied to the reagent layer provided on the specimen supply path, thereafter connecting the first selector switch to the ground,

applying a voltage between the working electrode and the counter electrode as well as the detecting electrode, and measuring a current generated by applying the voltage.

43. The quantification apparatus as defined in Claim 42 comprising:

a second selector switch for switching the connection of the working electrode of the biosensor to the second current/voltage conversion circuit or the ground, and

the control part

applying a voltage between the detecting electrode and the counter electrode as well as between the working electrode and the counter electrode in a state where the first selector switch is connected to the first current/voltage conversion

circuit and the second selector switch is connected to the second current/voltage conversion circuit, respectively,

connecting the second selector switch to the ground when detecting an electrical change between the working electrode and the counter electrode, occurring by the sample liquid which is supplied to the reagent layer provided on the specimen supply path, and

when thereafter detecting an electrical change between the detecting electrode and the working electrode, in a state where the second selector switch is connected to the second current/voltage conversion circuit and the first selector switch is connected to the ground,

applying a voltage between the working electrode and the counter electrode as well as the detecting electrode, and measuring a current generated by applying the voltage.

44. The quantification apparatus as defined in Claim 42 or 43 comprising an informing means for informing a user that no change occurs, when the sample liquid is supplied to the reagent layer of the specimen supply path, and the control part detects that an electrical change occurs between the working electrode and the counter electrode but no electrical change occurs between the detecting electrode and the working electrode or the counter electrode.